

# **EXHIBIT P**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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NOVO NORDISK A/S,

Plaintiff and Counterdefendant,

v.

AVENTIS PHARMACEUTICALS INC,  
SANOFI-AVENTIS, and AVENTIS  
PHARMA DEUTSCHLAND GMBH,

Defendants and Counterplaintiffs.

Case No. 1:05CV00645 SLR

**NOTICE OF SERVICE**

PLEASE TAKE NOTICE that on June 9, 2006, counsel for Plaintiff Novo Nordisk A/S served copies of Novo Nordisk A/S' Supplemental Responses to Aventis's First Set of Interrogatories to Plaintiff Novo Nordisk (Nos. 1-12) upon the following counsel of record in the manner indicated below:

**VIA HAND DELIVERY**


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*Attorneys for Plaintiff*

Dated: June 9, 2006

**UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I hereby certify that on June 9, 2006, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on June 9, 2006, I have sent by Federal Express the foregoing document to the following non-registered participants:

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**IN THE UNITED STATES DISTRICT COURT  
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NOVO NORDISK A/S,

Plaintiff and Counterdefendant,

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AVENTIS PHARMACEUTICALS INC,  
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PHARMA DEUTSCHLAND GMBH,

Defendants and Counterplaintiffs.

C.A. No. 05-00645-SLR

**NOVO NORDISK A/S' SUPPLEMENTAL RESPONSES TO AVENTIS'S  
FIRST SET OF INTERROGATORIES TO PLAINTIFF  
NOVO NORDISK (NOS. 1, 8 and 9)**

Plaintiff Novo Nordisk A/S ("Novo Nordisk") hereby amends and supplements its responses to Defendants' Aventis Pharmaceuticals Inc., sanofi-aventis and sanofi-aventis Deutschland GmbH (collectively, "Aventis") First Set of Interrogatories to Plaintiff Novo Nordisk (Nos. 1-12) ("First Set of Interrogatories") pursuant to Fed. R. Civ. P. Rules 26 and 33 and all applicable Local Rules.

**GENERAL OBJECTIONS**

1. Novo Nordisk incorporates by reference all of the objections set forth in Novo Nordisk's responses to Aventis's First Set of Interrogatories, as though fully set forth herein. The amendments and responses provided herein should not be construed as a waiver of any of the General or Specific Objections or responses previously provided.

**RESPONSE TO INTERROGATORIES****INTERROGATORY NO. 1**

State the factual and legal bases for Novo's allegations that Aventis infringes the patent-in-suit under 35 U.S.C § 271(a) (direct infringement), (b) (induced infringement), and (c) (contributory infringement), including but not limited to, the identity of each claim alleged to be infringed, the theory or theories (direct infringement, induced infringement, or contributory infringement) under which Novo alleges infringement for each such claim, the respective evidence that Novo believes supports each identified theory of infringement, the claim construction Novo proposes for each such claim, a claim chart providing the construction or interpretation of each such claim, the identity of each and every Aventis product alleged to infringe each such claim, a claim chart explaining how each element and limitation of each such claim is met by each Aventis product that Novo has accused of infringement, and an identification of whether such alleged infringement is literal, under the doctrine of equivalents, or both.

**RESPONSE**

Novo Nordisk objects to this request as premature to the extent it seeks identification of all or each of Aventis's infringing products because discovery has just begun and Aventis has not even produced documents to Novo Nordisk. Novo Nordisk also objects to this interrogatory in that it requests information that is protected from discovery by attorney-client privilege and attorney work product immunity. Novo Nordisk further objects to this interrogatory as overbroad and premature to the extent it calls for Novo Nordisk to provide a legal conclusion on the construction of all the limitations in the claims of the '408 patent. The Court's Scheduling Order provides an appropriate and agreed upon time for exchanging construction of disputed claim terms, and for construing the claims and variation from that schedule will unduly prejudice Novo Nordisk. Novo Nordisk further objects to this interrogatory as premature in that it calls for expert testimony. The Court's Scheduling Order sets forth an appropriate and agreed upon time frame for exchanging expert reports and taking expert discovery and variation from that schedule will unduly prejudice Novo Nordisk. Novo Nordisk expressly reserves the right to supplement its responses to this interrogatory to identify additional Aventis products that infringe one or

more claims of the '408 patent, as well as identify additional claims that are infringed by any Aventis product and to identify additional theories concerning Aventis's direct, contributory and inducement of infringement of the '408 patent as discovery reveals new information concerning Aventis's activities.

Based upon Novo Nordisk's current information, which does not include documents to be produced by Defendants in this case, and subject to Novo Nordisk's General and Specific objections, Novo Nordisk responds as follows:

Aventis is directly infringing the '408 patent by distributing, importing into the United States, selling and offering to sell at least OptiClik and components used with the OptiClik device. Aventis directly infringes at least claims 4, 6, 9, and 10 of the '408 patent.

Aventis induces infringement and contributes to infringement by others, such as, for example, patients, doctors and other medical personnel, by making, selling, offering for sale, distributing, manufacturing or importing into the United States OptiClik and by making, selling, offering for sale, distributing, manufacturing or importing into the United States components for use with OptiClik. Others, such as patients, doctors and other medical personnel, directly infringe the claims of the '408 patent by using OptiClik devices to administer medicament according to the instructions for use provided with OptiClik and the cartridges. Aventis induces infringement or contributes to infringement by others of at least claims 4, 6, 9 and 10 of the '408 patent either literally and/or under the doctrine of equivalents.

#### **SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 1**

The information set forth below is based upon information currently available to Novo Nordisk. Because discovery in this action is at its earliest phases, document production has just recently begun and is far from complete and Novo Nordisk has not yet completed its

investigation or review of documentation produced by the Defendants, Novo Nordisk reserves the right to modify, amend, supplement and replace the following to reflect additional claims, evidence, and other information obtained through further investigation, analysis and/or discovery.

The chart below, provided for exemplary purposes only, demonstrates how the OptiClik device and its components meet the limitations of the claims of the '408 patent.

| Claim  |  |
|--|--|
| 4. A medication delivery device upon which a needle assembly can be mounted, the device comprising:  | The OptiClik Instruction leaflet describes OptiClik as “[a] reusable insulin delivery device (insulin Pen) for use with 3 ml Lantus or Apidra cartridge (U-100) systems.” Needle assemblies can be, and are intended to be, mounted on the cartridge systems and are, in fact, sold or distributed in combination with the OptiClik insulin delivery device.<br><br>(SAN00000009-10; SAN00000011; SAN00000002; SAN00000004; SAN00000013-14.) |
| a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;  | The OptiClik insulin delivery device including its component parts comprises a cartridge assembly that comprises a cartridge, a moveable stopper at one end and a rubber, pierceable seal at the opposite end from the stopper.<br><br>(SAN00000004; SAN00000011-14.)  |
| a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set dosage; | The OptiClik insulin delivery device including its component parts comprises a dosage assembly that in turn comprises a dosage mechanism for setting the dose of insulin in the form of a dosage “knob,” a plunger means for abutting a stopper in the cartridge assembly and a drive means for driving the plunger means and delivering the set dose.<br><br>(SAN00000009-10, SAN00000015-16.)  |



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| a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and  | <p>The OptiClik insulin delivery device including its component parts comprises a coupling that permits the cartridge assembly to be coupled to, and uncoupled from, the dosage assembly. The cartridge assemblies used with the OptiClik device reversibly “click” into place by means of the coupling means between the cartridge assembly and the dosage assembly.</p> <p>(SAN00000010; SAN00000013; SAN00000017.)</p>    |
| a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;   | <p>The OptiClik insulin delivery device including its component parts comprises a coupling that permits the needle assembly to be coupled to and uncoupled from the cartridge assembly by virtue of a threaded coupling.</p> <p>(SAN00000010; SAN00000013-14; SAN00000016-17.)</p>   |
| wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper; and | <p>The OptiClik insulin delivery device including its component parts comprises first and second couplings in the form of a snap-lock assembly and a threaded coupling that ensure that the dosage assembly and the cartridge assembly do not move relative to each other during coupling and uncoupling of the needle assembly and that the plunger means remains abutted against the stopper.</p> <p>(SAN00000013-14.)</p> |
| wherein the first or second coupling means comprises a snap lock.   | <p>The coupling means between the cartridge assembly and the dosage assembly of the OptiClik device comprises a snap lock.</p> <p>(SAN00000010.)</p>   |
| 5. The medication delivery device recited in claim 4, wherein   | See Claim 4.   |
| the second coupling means comprises a threaded coupling   | The OptiClik insulin delivery device, when combined with its component parts, includes a threaded connection for connecting the cartridge assembly with a needle or needle   |

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| means and  | assembly. The threaded connection receives a needle or needle assembly that is screwed in place on the cartridge assembly.<br><br>(SAN00000014.)   |
| wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly. | The act of coupling and uncoupling the threaded needle or needle assembly from the cartridge assembly requires axial movement of the needle assembly relative to the cartridge assembly.<br><br>(SAN00000010; SAN00000014.)  |
| 6. The medication delivery device of claim 4, wherein  | See Claim 4.   |
| the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.                       | Uncoupling the cartridge assembly from the dosing assembly of the OptiClik insulin delivery device is accomplished through an axial movement of the cartridge assembly relative to the dosing assembly.<br><br>(SAN00000010, SAN00000017.)   |
| 9. The medication delivery device of claim 4, wherein  | See Claim 4.   |
| the second coupling means comprises a threaded coupling means.   | The OptiClik insulin delivery device, when combined with its component parts, includes a threaded connection for connecting the cartridge assembly with a needle or needle assembly. The threaded connection receives a needle or needle assembly that is screwed in place on the cartridge assembly.<br><br>(SAN00000014.)  |
| 10. A medication delivery device comprising:   | The OptiClik Instruction leaflet describes OptiClik as “[a] reusable insulin delivery device (insulin Pen) for use with 3 ml Lantus or Apidra cartridge (U-100) systems.” Needle assemblies can be, and are intended to be, mounted on the cartridge systems and are, in fact, sold or distributed in combination with the OptiClik insulin delivery device.<br><br>(SAN00000009-10; SAN00000011; SAN00000002; SAN00000004; SAN00000013-14.) |
| a cartridge assembly comprising: a housing capable of housing a  | The OptiClik insulin delivery device including its component parts comprises a cartridge assembly that includes a plastic  |

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| removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and   | housing that holds a removable insulin filled ampoule cartridge. The ampoule cartridge is sealed by a rubber seal that is pierced when a needle or needle assembly is attached to the cartridge assembly. The cartridge also includes a stopper at the opposite end of the pierceable seal that, when moved toward the medication, pressurizes the medication.<br><br>(SAN00000004; SAN00000013.)  |
| a needle mounting means for mounting a needle on the cartridge assembly;  | The cartridge assemblies used with the OptiClik device include connections for mounting a needle.<br><br>(SAN00000014.)  |
| a dosage assembly for delivering a set dose of medication, comprising: a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper; | The OptiClik insulin delivery device including its component parts comprises a dosage assembly that delivers a set dose of medication. The user sets the required dose by turning the dosage "knob." The user then depresses the "knob" which activates the drive means, drives a plunger, moves the stopper, and expels medication from the cartridge in the amount of the set dose. After a dose is delivered, the plunger remains abutted against the stopper.<br><br>(SAN00000009-10, SAN00000015-16.) |
| a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly;   | The OptiClik insulin delivery device including its component parts comprises a coupling that permits the needle assembly to be coupled to and uncoupled from the cartridge assembly by virtue of a threaded coupling.<br><br>(SAN00000010; SAN00000013-14; SAN00000016-17.)  |
| a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly;  | The OptiClik insulin delivery device including its component parts comprises a coupling that permits the cartridge assembly to be coupled to, and uncoupled from, the dosage assembly. The cartridge systems used with the OptiClik device reversibly "click" into place by means of the coupling means between the cartridge assembly and the dosage assembly.<br><br>(SAN00000010; SAN00000013; SAN00000017.)  |
| wherein the first and second coupling means are chosen so that when a user simultaneously   | The OptiClik insulin delivery device including its component parts comprises a snap-lock and a threaded coupling that ensure that the dosage assembly and the cartridge assembly   |

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|--|--|
| grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the dosage assembly; and | do not move axially relative to each other when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device.<br><br>(SAN00000013-14.) |
| wherein at least the first or the second coupling means comprises a snap lock.   | The coupling means between the cartridge assembly and the dosage assembly of the OptiClik device comprises a snap lock.<br><br>(SAN00000010.)  |

Each of the limitations of the claims of the '408 patent is literally present in the OptiClik insulin delivery device including its components. Novo Nordisk, however, reserves the right to assert infringement under the doctrine of equivalents.

Aventis is directly infringing the '408 patent by distributing, importing into the United States, selling and offering to sell at least OptiClik and components used with the OptiClik insulin delivery device, including the Lantus and Apidra cartridge systems to be used with the OptiClik device.

Aventis also induces infringement by others, such as, for example, patients, doctors and other medical personnel, by making, selling, offering for sale, distributing, manufacturing or importing into the United States the OptiClik insulin delivery device and its components including the Lantus and Apidra cartridge systems with knowledge that the aforementioned third parties, and others, would assemble the OptiClik insulin delivery device and its components and use the alleged infringing device. Aventis, in fact, provides explicit directions on assembling the components into, and then using, the infringing device. (See, e.g., SAN00000011-SAN00000022.) Accordingly, Aventis induces infringement of claims 4, 5, 6, 9 and 10.

Aventis also contributes to the infringement by others, such as, for example, patients, doctors and other medical personnel, by selling, offering for sale, distributing, or importing into the United States material components of the claimed invention with knowledge of the specific use of the OptiClik device and its components. The material components that Aventis sells, offers for sale, distributes or imports into the United States include the OptiClik insulin delivery device, the dosing assembly of the OptiClik insulin delivery device, and the Lantus and Apidra cartridge assemblies, none of which are staple articles of commerce or have non-infringing uses. Accordingly, Aventis contributes to the infringement of claims 4, 5, 6, 9 and 10 of the '408 patent by selling, offering for sale, distributing, or importing into the United States the OptiClik insulin delivery device, Lantus cartridge systems and Apidra cartridge systems.

#### **INTERROGATORY NO. 8**

Provide the name, current employer, title or position, address or last known address, and telephone number or last known telephone number of each inventor named on the patent-in-suit and of each individual who participated or assisted in the preparation of the application(s) that resulted in the patent-in-suit, who participated or assisted in the prosecution of the patent-in-suit and/or any related or counterpart foreign patent applications, and who participated in decisions to file patent application(s), request examination of, not request examination of, pay maintenance fees for, or not pay maintenance fees for, or abandon any of the patent-in-suit or related or counterpart foreign patent applications.

#### **RESPONSE**

Novo Nordisk objects to this request as overly broad and vague in its use of the terms "participated" and "assisted in." Novo Nordisk also objects to this interrogatory in that it requests information that is protected from discovery by attorney-client privilege and attorney work product immunity. Novo Nordisk further objects to this request as overbroad, unduly burdensome and not likely to lead to discovery of admissible evidence to the extent it seeks information concerning present and former Novo Nordisk employees and attorneys, which encompasses potentially thousands of people having no substantive involvement in the

prosecution of the application that led to the '408 patent. Novo Nordisk also objects to this interrogatory to the extent it seeks information beyond that required by Rule 26 of the Federal Rules of Civil Procedure.

Novo Nordisk also objects to this interrogatory as unduly burdensome to the extent that determination of the persons having substantive involvement in the prosecution of any relevant application can be readily ascertained by inspecting the file histories and the burden of ascertaining such information is substantially the same for Aventis as it is for Novo Nordisk.

Subject to the foregoing general and specific objections, Novo Nordisk responds as follows:

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Any contact with the inventors of the '408 patent can and should be made through their attorneys, White & Case LLP.



**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 8**

Subject to the General and Specific Objection previously set forth, Novo Nordisk also identifies the following persons in response to Interrogatory No. 8:

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Any contact with the individuals named herein can and should be made through their attorneys, White & Case LLP.

**INTERROGATORY NO. 9**

Identify all pre-July 8, 1999 references, Medication Delivery Devices (whether made by Novo or another), Related Products, and/or prior art known to Novo that relate to the subject matter taught and/or claimed in the '408 patent, and for each such reference, Medication Delivery Device, Related Product, and instance of prior art, state whether it discloses: a coupling means for coupling and/or uncoupling a needle assembly to and/or from a cartridge assembly, a coupling means for coupling and/or uncoupling a cartridge assembly to and/or from a dosage assembly, a snap lock, a releasable snap lock, a snap lock with guidewire, a sideways snap lock, a snap lock released through threads, a bayonet (or bajonet) lock, a luer lock, a hinged lock, a threaded lock, or a snap coupling, or a coupling means that comprises a snap lock, releasable snap lock, snap lock with guidewire, sideways snap lock, snap lock released through threads, bayonet (or bajonet) lock, luer lock, hinged lock, threaded lock, or snap coupling, and/or whether or not a cartridge assembly can move relative to a dosage assembly (or vice versa) when a user couples or uncouples a needle assembly; state the date that each such reference, Medication Delivery Device, Related Product, or prior art came to the attention of Novo; and for each such Medication Delivery Device and Related Product, state who made the device, whether the device was sold in the United States or anywhere else in the world, and identify any entities or persons

that marketed, sold, or offered for sale the device in the United States or anywhere in the world; and identify all documents and things that refer and/or relate to the foregoing, identify the person or persons most knowledgeable about the foregoing, and identify whether or not each person identified in response to Interrogatory No. 8 knew of each such reference, Medication Delivery Device, Related Product, or instance of prior art

## **RESPONSE**

Novo Nordisk objects to this interrogatory as vague and ambiguous in that the scope of the phrase “that relate to” is indeterminate and the terms “known” and “knew” are unlimited in time, making the request incomprehensible. Novo Nordisk further objects to this interrogatory as requesting information protected from disclosure by attorney-client privilege and work product immunity. Novo Nordisk objects to this interrogatory on the basis that it is compound and harassing, and seeks to avoid the limitation on the number of interrogatories imposed by the Court’s Scheduling Order by seeking information about multiple topics. Compliance with such an interrogatory is unduly burdensome.

Novo Nordisk objects to this interrogatory to the extent it purports that any pre-July 8, 1999 reference, Medication Delivery Devices or Related Products (as those terms are defined by Aventis) is prior art to the ’408 patent. Nothing contained in Novo Nordisk’s response should be construed as an admission that any pre-July 8, 1999 reference, Medication Delivery Devices or Related Products (as those terms are defined by Aventis) constitutes prior art. Novo Nordisk also objects to this interrogatory as overly broad and not likely to lead to discovery of admissible information in that it requests information regarding sales “anywhere else in the world.”

Novo Nordisk objects to this interrogatory as unduly burdensome and premature in that it calls for a legal conclusion to determine what constitutes “prior art,” legal conclusions in the form of construing multiple claim terms, and legal conclusions in defining the claimed invention to ascertain what relates to the “subject matter taught and/or claimed in the ’408 patent.” As drafted, Aventis’s interrogatory cannot possibly be answered because it contains no identification



of specific prior art references or articles. Aventis has the burden of proving invalidity of the '408 patent by clear and convincing evidence and to date has provided no identification of any prior art relating to the '408 patent. Thus, Novo Nordisk has no prior art invalidity contentions to respond to and reserves the right to supplement its response at a proper time when Aventis has fully identified the prior art on which it seeks to rely. The Court's Scheduling Order provides an appropriate and agreed upon time for exchanging construction of disputed claim terms, and for construing the claims and variation from that schedule will unduly prejudice Novo Nordisk. Novo Nordisk further objects to this interrogatory as premature in that it calls for expert testimony. The Court's Scheduling Order sets forth an appropriate and agreed upon time frame for exchanging expert reports and taking expert discovery and variation from that schedule will unduly prejudice Novo Nordisk.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 9**

Novo Nordisk will produce documents under Rule 33(d) from which Aventis can identify pre-July 8, 1999 references, products or devices, if any, relating to the asserted claims of the '408 patent. Novo Nordisk will also produce documents under Rule 33(d) from which Aventis, itself, can discern the presence or absence of each of the claimed limitations recited in Interrogatory No. 9. Identification of any documents from which a response to Interrogatory No. 9 can be discerned should not be construed as indicating that Novo Nordisk had knowledge of any reference, device or product at any time as the phrase "known to Novo" remains incomprehensible. In addition, production of a document should in no way be construed as an admission that a reference is relevant prior art to the '408 patent. Novo Nordisk will agree to provide existing Novo Nordisk products and devices for Aventis's inspection concurrent with an

inspection of current Aventis products and devices by Novo Nordisk as agreed upon by the parties.

As to Objections,

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Dated: June 9, 2006

**CERTIFICATE OF SERVICE**

I hereby certify that on June 9, 2006, I caused to be served by hand delivery the foregoing document to the following:

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